The invention relates to improvements in extended dwell voice prosthesis that remains in direct contact with the stoma for long periods. The valve of the prosthesis becomes encrusted with growth of microbial materials interfering with its function and shortening the period the prosthesis can remain in place. In attempts to improve the dwell period of the prosthesis, the outside wall and valve were compounded with antimicrobial materials. It was discovered that the stoma tissue in direct contact with the outside surface of the prosthesis became irritated over the extended dwell of the prosthesis.

The invention relates to the discovery that adding antimicrobial materials to the outside surface of the valve at an effective level, does not cause irritation of the tissue of the stoma which is only in indirect fluid contact with the antimicrobial outside surface of the valve. The outside surface of the prosthetic can contain a low, non-irritating and non-toxic level of antimicrobial agents.

The invention is not disclosed nor rendered obvious by the cited references.

Laguette discloses a tubular, silicone voice prosthesis. Prescott discloses adding triclosan to a polymer for a prosthetic device such as a voice prosthesis in a range of 0.5 to 5% by weight. However there is no teaching nor suggestion to add an amount of triclosan effective to disrupt microbial growth only to the valve and add a lower, non-irritating amount of antimicrobial material to the surfaces of the voice prosthesis in direct contact with tissue.

The incidentally cited references have been reviewed and are believed to be less relevant than the references applied to reject the claims.

For the above reasons this application is believed to be in

condition for allowance and such action at an early date is respectfully solicited.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231

11-8-02 _____

Date Signature

Marked-up Version of Claims Showing Changes Made

1. Depositing a biofilm;

2. Feeding and attack by microbes of bacteria origin;

3. Feeding and attack by yeast;

and said antimicrobial activity is provided by inhibiting or interfering with at least one of said steps.

17. A voice prosthesis for use in contact with tissue comprising in combination:

a tubular body having a central channel and an annular wall having an inside surface not in contact with tissue and an outside surface in contact with tissue and containing antimicrobial material at a level that is non-irritating and non-toxic to tissue;

a valve having an inside surface and an outside surface and being mounted to seal and intermittently open said channel, said out side surface of the valve being in contact with body fluids; and

the outside surface of the valve not being in direct contact with tissue and having antimicrobial properties [such that tissue in contact with said outside surface is irritated by and/or toxic to said surface] at a level that would irritate or be toxic to that tissue.

18. A voice prosthesis according to claim 17 in which the outside surface of the [body] wall is in contact with tissue and the outside surface of the [body] wall is non-irritating to and non-toxic to said tissue.

19. A voice prosthesis according to claim 18 in which said body and said valve are formed of an elastomer.

20. A voice prosthesis according to claim 19 in which the valve is formed of a silicone elastomer containing a dispersion [of] or outside coating of an antimicrobial

material.

21. A voice prosthesis according to claim 20 in which the antimicrobial material is selected from metal [and] salts, [and] metal oxides [thereof] and organic antimicrobial materials.

22. A voice prosthesis according to claim 21 in which the material is selected from silver oxide in an amount from 6 to at least 50 phr and butyl paraben [and] or triclosan in an amount from 0.2 to 5% by weight dispersed in the resin forming the valve.